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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/432,503 11/02/99 CECH

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EXAMINER

HM12/0327

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ART UNIT

PAPER NUMBER

1652

DATE MAILED:

03/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

# Office Action Summary

Application No.  
09/432,503

Applicant(s)

Cech et al.

Examiner  
Maryam Monshipouri

Group Art Unit  
1652



- ☐ Responsive to communication(s) filed on \_\_\_\_\_
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

- ☒ Claim(s) 1-22 \_\_\_\_\_ is/are pending in the application.
- Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☒ Claims 1-22 \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- ☐ Notice of References Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, drawn to an isolated human telomerase reverse transcriptase (hTERT), classified in class 435, subclass 194 .
- II. Claims 2-3 , 10 and 21-22, drawn to a synthetic polynucleotide of at least 10 nucleotides in length that is identical or complementary to a DNA sequence encoding hTERT and a method of increasing the proliferative capacity of a cell by introducing a recombinant hTERT into the cell wherein said sequence is operatively linked to a promoter, classified in class 435, subclass 375.
- III. Claims 4-5, drawn to a compound that modulates hTERT activity classification classified in class 536, subclass 23.2.
- IV. Claims 6-9, drawn to a method of preparing recombinant telomerase comprising contacting hTERT with a telomerase RNA component under conditions that said telomerase associate with said protein, classified in class 435 , subclass 194.
- V. Claims 11-16, drawn to a method of detecting the presence of at least one telomerase positive human cell in sample comprising measuring the amount of hTERT gene product in said sample, classified in class 435, subclass 6.
- VI. Claims 17-20, drawn to a method of treatment comprising introducing a therapeutically effective amount of inhibitor of telomerase activity where the inhibitor is an inhibitor of hTERT etc., classified in class 424, subclass 130.1.

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The inventions are distinct, each from the other because of the following reasons:

The hTRT polypeptide of Group I, the polynucleotides of Group II, and hTRT modulators of Group III are each patentably distinct from the other because each product has an independent chemical structure and function.

Inventions I and IV or V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case hTRT polypeptide of Group I may be used in antibody preparation which is an entirely different method than that of Groups IV-V.

The hTRT polypeptide of Group I is unrelated to the method of Group VI because said product is neither made nor used by said method.

The polynucleotides of Group II are unrelated to methods of Group IV, V or VI because said products are neither made nor used by said methods.

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Inventions III and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case hTRT antibodies may be used in the method of Group VI which are entirely different products than the modulators of Group III.

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The modulators of Group III are unrelated to the methods of Group IV or V because said products are neither made nor used by said methods.

The methods of Group IV, V and VI are patentably distinct each from the other because each method has separate steps and separate end-points.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter as shown by their separate classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Maryam Monshipouri, Ph.D. whose telephone number is (703) 308-1083. The examiner can normally be reached between 8:00 a.m. and 5:00 p.m. daily except for Fridays.

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. P. Achutamurthy, can be reached at (703) 308-3804. The OFFICIAL fax number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

*re: Achutamurthy*

Maryam Monshipouri, Ph.D.

Patent Examiner

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